



K024086

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JAN 09 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc
56 E. Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Kacy Arnold, RN, MBA
Telephone: (574) 372-1644
Fax: (574) 372-1683

Proprietary Name: Propeller Head Small Cannulated Screw System

Common or Usual Name: Bone Screw

Device Classification: Screw, Fixation, Bone (888.3040)

Device Product Code: 87HWC

**Legally Marketed Devices
To Which Substantial
Equivalence Is Claimed:** Self-Countersinking Bone Screw (K013534)

Indications for Use: The Propeller Head Small Cannulated Screw System is indicated for the following conditions:

- Fixation of fractures in long bones such as the fibula, tibia, humerus, radius and ulna as well as fractures in the patella.
- Fixation of the small bones such as those in the foot, ankle, wrist and elbow.
- Ligament reconstruction
- Arthrodesis of the foot, ankle, wrist and elbow.
- Small bone osteotomies

Device Description: The Propeller Head Small Cannulated Screw System is a titanium screw that has cutting flutes in the head, which allows it to cut into the bone, thus countersinking itself. The screw is also cannulated to allow insertion over a guide wire. The threads are self-drilling and self-tapping.

Non-Clinical Testing: Mechanical testing demonstrated the modified device performed as well as or better than the previously marketed devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 09 2003

Kacy Arnold, RN, MBA
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K024086

Trade/Device Name: Propeller Head Small Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 9, 2002
Received: December 11, 2002

Dear Ms. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

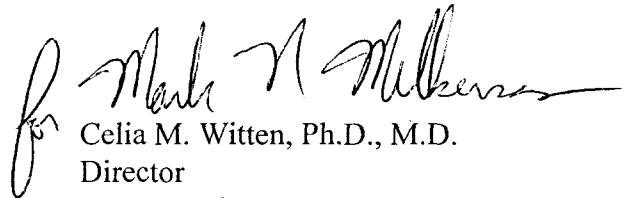
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

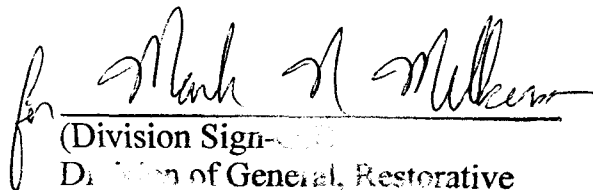
Enclosure

510 (k) Number (if known) : K024086

Device Name: Propeller Head Small Cannulated Screw System

Indications for Use: The Propeller Head Small Cannulated Screw System is indicated for the following conditions:

- Fixation of fractures in long bones.
- Fixation of the small bones, including those in the foot, patella, ankle, wrist and elbow.
- Ligament reconstruction
- Arthrodesis of the foot, ankle, wrist and elbow.
- Small bone osteotomies
- Osteochondritis dissecans



(Division Signatory)
Division of General, Restorative
and Neurological Devices

510(k) Number K024086

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)